



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,823	07/08/2005	Andreas Katopodis	TX/4-32561A	4724
1095	7590	02/26/2008		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER BELYAVSKIY, MICHAEL A	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 02/26/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/522,823

**Applicant(s)**

KATOPODIS ET AL.

**Examiner**

Michail A. Belyavskyi

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 3-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's amendment, filed 11/27/07 is acknowledged.

*Claims 1-13 are pending.*

2. Applicant's election of Group II, claim 2, now claims 2 and 13 in the reply filed on 11/27/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1, 3-12 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

*Claims 2 and 13 read on a method for inducing hematopoietic chimerism in a recipient of cells comprising administering to the recipient bone marrow cells, a LFA-1 inhibitor in combination with costimulation inhibitor or mTOR inhibitor are under consideration in the instant application.*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.*

5. Claims 2 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by WO' 01/95928(IDS).

Art Unit: 1644

WO' 928 teaches a method of inducing hematopoietic chimerism in a recipient comprising steps of administering a bone marrow cells anti-LFA-1 inhibitor, co-stimulation inhibitor ( anti-CD28 or anti- CD40/CD154) and immunosuppressant ( see entire document, Abstract and pages 4 and 8 in particular).

The reference teaching anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,653,282 or WO 95/34320 each in view of US Patent 6,486,209 and US 2002/01524900

US Patent '282 teaches a method of inducing immune tolerance during organ, tissue or cell transplantation including bone marrow transplantation, i.e. inducing hematopoietic chimerism, comprising administering to the subject a combine therapy of LFA-1 inhibitor and co-stimulatory inhibitor ( see entire document, Abstract, and column 2 in particular).

WO' 320 teaches a method of inducing immune tolerance during organ, tissue or cell transplantation, including bone marrow transplantation, i.e. inducing hematopoietic chimerism, comprising administering to the subject a combine therapy of LFA-1 inhibitor and co-stimulatory inhibitor( anti-CD28 or anti- CD40/CD154, etc) ( see entire document, Abstract and pages 3, 4, 8, 19 and 22 in particular).

The claimed invention differs from the reference teaching in that US Patent '282 or WO' 320 does not exemplify teaches a method of inducing hematopoietic chimerism, comprising administering a combination of LFA-1 inhibitor, co-stimulation inhibitor and immunosuppressive inhibitor 15-deoxyspergualine.

US Patent ' 209 teaches a method of transplantation of organ, tissue or cell comprising administering to the subject an immunosuppressive inhibitor 15-deoxyspergualine ( see entire document, Abstract, column 5 and claim 1 in particular).

Art Unit: 1644

US '490 teaches a method for inducing hematopoietic chimerism in a subject comprising administering a conventional immunosuppressant treatment using 15-deoxyspergualine ( see entire document, page 4 in particular).

All the claimed elements were known in the prior art and one skill in the art could have combine the elements as claimed by known methods with no change in their respective function and the combination would have yield predictable results to one of ordinary skill in the art at the time of the invention ( see *KSR International Co v Teleflex Inc.*, 550U.S.-, 82 USPQ2d 1385, 2007).

Thus it would have been obvious to one of the ordinary skill in the art at the time the invention was made to combine a conventional immunosuppressant treatment with 15-deoxyspergualine and a combination of LFA-1 inhibitor and co-stimulation inhibitor (anti-CD28 or anti-CD40/CD154, etc) for inducing hematopoietic chimerism with a reasonable expectation of success. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571/272-0878.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAIL BELYAVSKYI, PH.D.  
PRIMARY EXAMINER

2/15/08